REMARKS

Drawings

Formal drawings are enclosed.

Claim objections

The minor informalities in the claims have been corrected in accordance with the examiner's suggestions.

Rejection under 35 U.S.C. §101

The claims have been amended to recite that they are "transformed cells." This phrase is fully supported in the specification, e.g., on Page 5, lines 1-13; Page 79, lines 15-16 and 31-32. This amendment does not change the scope of the claims in any way, but is merely to conform the claims to conventional U.S. claim format. In particular, the original claims would have been understood by the skilled worker to involve transformed cells.

Rejection under 35 U.S.C. §112, second paragraph

The original claims as filed were a translation of a German priority document. As a result of both language differences and differences in the practices between the U.S. and foreign (German, European, etc.) patent offices, a series of amendments have been made to the claims for purposes of clarity and conforming them to local U.S. practice. These amendments are not intended to narrow the claims, but merely to clarify for them.

The claims have been amended to clarify that the membrane receptor and fusion protein are present in the transformed cell, and that the fusion protein comprises an effector polypeptide fused to an adaptor polypeptide.

The term "ras-like" would be understood by the skilled worker, e.g., as described in Schlessinger, *TIBS*, 18:273-275, 1993 and other references. See, Specification, Page 6, lines 1-3.

Rejection under 35 U.S.C. §112, first paragraph

The specification provides clear enablement and description for the full scope of the claims. According to M.P.E.P. §2164.04: "In order to make a rejection, the examiner has the

initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. In re Wright, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure). A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support."

The *Eli Lilly* case is cited in support of the alleged deficiency in the written description of the claimed subject matter. However, *Eli Lilly* involved claiming specific cDNA sequences coding for mammalian insulin. In these circumstances, the court found that "a description of rat insulin cDNA is not a description of the broad classes of vertebrate or mammalian insulin cDNA." *Regents of University of California v. Eli Lilly*, 119 F.3d. 1559; 43 USPQ2d 1398 (Fed. Cir. 1997). In the original claims of the pending application, the claims recited classes of proteins which were well known in the art. As a consequence, at the time the application was filed, the applicant would have had possession of a large number of proteins which fell within the scope of the claims.

Rejection under 35 U.S.C. §102 and 103

The prior art references do not disclose or suggest, e.g., a transformed cell comprising, a human epidermal growth factor type membrane receptor and a fusion protein comprising an effector polypeptide which is a constitutively active human ras polypeptide fused to an adaptor polypeptide, wherein upon binding of ligand to said receptor, said fusion protein binds to said receptor via said adaptor polypeptide. The references, such as Trueheart (U.S. Pat. No. 6,159,705), do not provide any motivation coupled with a reasonable expectation of success that the claimed receptor and fusion protein when present in a transformed cell would, e.g., be able to activate the Ras or Ras-like signal pathway. Compare, e.g., Claim 35, 43, 46, etc.

The Examiner must show that the cited references coupled with the general knowledge at the time of the invention contains some suggestion or incentive to motivate a skilled artisan to modify a reference or to combine references to achieve the claimed

invention. *See In re Fine,* 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Further, the requisite motivation must flow from some teaching in the references that suggests the desirability or incentive to arrive at the claimed invention. *See In re Napier*, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir 1995) ("Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination."). The cited references do not contain such a suggestion or incentive.

The Examiner must also show that the modification or combination of cited references must have a reasonable expectation of success. As stated above, this reasonable expectation of success must be provided by the cited references, not applicants' disclosure. *Id.* The cited references, singly or in combination, do not mention or suggest the claimed invention. Thus, not only would the skilled artisan not be motivated to use the teachings of these references to arrive at the present invention, but also the skilled artisan would not have a reasonable expectation of success in view of the teachings in the cited references.

The Commissioner is hereby authorized to charge fees under 37 CFR § 1.16 and § 1.17 which may be required to facilitate this filing, or credit any overpayment to Deposit Account #13-3402.

Respectfully submitted,

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